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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/769,878	01/25/2001	John E. Sims	2976-B	7821

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EXAMINER	
HAMUD, FOZIA M	

ART UNIT	PAPER NUMBER
1647	11

DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Filc 97

Office Action Summary	Application No.	Applicant(s)	
	09/769,878	SIMS, JOHN E.	
	Examiner	Art Unit	
	Fozia M Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,8,9,11,15 and 17-38* is/are pending in the application.

4a) Of the above claim(s) *8,9 and 18-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1,11,15,17 and 32-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Detailed Office Action

1. Receipt of Applicants' arguments and amendments filed in Paper No.9, filed on 04 March 2003 is acknowledged. Claims 2-7, 10, 12, 13, 14 and 16 have been canceled, claims 1, 11 and 15 have been amended and new claims 32-38 have been added.

Election/Restrictions

2. During a telephone conversation with Janis Henry on 13 August 2002, a provisional election was made with traverse to prosecute the invention of Group I (claims 1-7, 10-17, i.e., SEQ ID NO:3 encoding SEQ ID NO:4). Applicants were asked to Affirm this election when responding to the previous Office action. Because applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The restriction requirement is still deemed proper and is therefore made FINAL.

Claims 1, 8-9, 11, 15, 17-38 are pending. Claims 1, 11, 15, 17 and 32-38 are drawn to the elected invention. Claims 8-9, 18-31 stand withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

Response to Amendment:

3. *The following previous objections and rejections are withdrawn in light of Applicants amendment filed in Paper No.6, 03/04/03:*

(I) The objection to the specification for containing an embedded hyperlink.

(II) The objection to claim 1.

(III) The rejection of claims1-7 and 10-17 made under 35 U.S.C § *102*(e) as being anticipated by Ballinger et al (U.S. Patent 6,339,141).

Claim Rejections - 35 U.S.C. § 101/112

4a. Claims 1, 11, 15, 17 stand rejected, and new claims 32-38 are rejected under 35 U.S.C. §101 for reasons of record set forth in the office action mailed on 21 August 2002 in Paper NO:7, pages 4-8.

Applicants argue that the utility or lack thereof of a polypeptide or polypeptides is not pertinent to the present claims, because the utility of the claimed invention is based on the utility of the nucleic acids themselves. Applicants assert that the DNA of SEQ ID NO:1 maps to human chromosome 2, 2q11-12, and since several disease states map on said chromosome, those skilled in the art can use the claimed nucleic acids to analyze abnormalities associated with genes mapping to chromosome 2.

Applicants' second argument is that since Applicants have identified polymorphism associated with particular member of the iL-1 family, at amino acids 44 and 51, oligonucleotides that encompass any of the alleles associated with these amino acids are useful fro detecting polymorphisms associated with disease. Applicants contend that these utilities are specific, since they are not shared by every nucleic acid or oligonucleotide, said utilities are also substantial, because use of the claimed nucleic acid to analyze abnormalities with genes mapping to chromosome 2 and for detecting polymorphism associated with disease are reasonable uses that provide a clear public benefit.

Applicants' arguments have been fully considered, but are not deemed persuasive. With respect to Applicants' first argument, not only the polypeptide encoded by the claimed nucleic acid lacks utility, but the nucleic acid itself also lacks utility. The fact that the claimed nucleic acid maps on human chromosome 2, 2q11-12, does not provide specific or substantial utility for the claimed nucleic acid. Applicants' contention that several diseases map on said chromosome is accurate, however, Applicants have not shown which of these diseases is associated with the claimed nucleic acid. Applicants have not shown whether the claimed nucleic acid is associated with glaucoma, ectodermal dysplasia, insulin-dependent diabetes mellitus, or any of the other diseases that map on this chromosome, or if it is involved in all of the diseases that map on this chromosome. Neither have Applicants shown whether the claimed nucleic acid is over expressed or under expressed in any disorder. Applicants cite Dale et al (Exhibit 1), as demonstrating a real world utility for nucleic acids that facilitate mapping of the region of chromosome 2, to which several members of the IL-1 family have been mapped. However, the Dale et al reference only teaches the placement and orientation of several IL-1 receptor family members on chromosome 2, and asserts that these might be useful as a resource for sequencing and identification of polymorphic markers. This reference does not disclose whether the claimed nucleic acid is associated with any of the diseases that map on human chromosome 2.

With respect to Applicants' second argument, the prior art is silent with regard to polymorphisms on amino acids 44 and 51 of instant SEQ ID NO:4.

There is doubt that IL-1 polymorphism associated with specific disease is useful in determining subjects that might be susceptible for a certain condition. Applicants have cited U.S. Patent 6,268,142, which discloses specific IL-1 polymorphism, associated with specific conditions. The Patent discloses, for example, that individuals with 44112332 halotype typically over producer both IL-1 alpha and IL-1 beta, while individuals with 33221461 halotype typically under produce IL-1ra, resulting in a net pro-inflammatory response in both groups, (see column 14, lines 1-66). Thus, the use of specific IL-1 polymorphism in identifying subjects that might be predisposed for certain condition has utility, provided that said polymorphism is associated with a certain condition or disease. Instant specification only discloses the detection of polymorphism of the polypeptide of SEQ ID NO:4 at amino acids 44 and 51, in some of the analyzed samples, (see pages 57-58). However, Applicants have not attached any disorder or disease to the occurrence of these polymorphisms. There is a large body of knowledge in the prior art related to polymorphisms in general, and their association with diseases or disease states. The art is highly unpredictable with regard to the functionality of polymorphic sites in genomic DNA. After a screening assay identifies polymorphisms, it is unpredictable whether any such polymorphisms would be associated with any phenotypic trait, such as a disease state or a physiological state. For example, Hacker et al. were unable to confirm an association between a gene polymorphism and ulcerative colitis in a case where prior studies suggested such a relationship would exist since the relationship had been identified in a different population (Gut, 1997, Vol. 40, pages 623-627).

Even in cases where an association between a particular gene and a disease state is known to exist, such as with the LPL gene and heart disease risk or the β-globin gene and sickle cell anemia, researchers have found that when using SNP (single nucleotide polymorphism analysis) it was difficult to associate SNPs with disease states or to even identify key genes as being associated with disease (Pennisi, Science, 281 (5384):1787-1789). Thus, even for SNPs within the same gene, it is highly unpredictable as to whether a particular marker will be disease associated.

The level of skill in the pertinent art is quite high, i.e. generally a PhD in biochemistry, but the unpredictability in the art is higher. While the instant specification has disclosed two polymorphisms in SEQ ID NO:3, it remains highly unpredictable as to the biological significance of these polymorphisms. Even if the elected polymorphism is in some way associated with some disease, it is difficult (if not impossible) to know or predict from the teachings of the specification which disease or how the polymorphism is associated. That is, it is unpredictable as to whether the presence of a particular allele the polymorphism would confer a higher or lower likelihood of having the disease. In this case, detecting polymorphism in some of the analyzed samples, does not provide the claimed nucleic acid utility, since Applicants have not attached any condition or disease to said polymorphism.

Therefore, the claimed nucleic acid lacks substantial utility, because Applicants have not taught which abnormalities that map to chromosome 2 can the claimed nucleic acid be used to identify. Furthermore, the polymorphisms

identified for the nucleic acid of SEQ ID NO:3, are not associated with a specific condition, as a result, one of ordinary skill in the art would be able to predict which conditions that might be associated with these polymorphisms.

4b. Claims 1, 11, 15, 17 and new claims 32-38 stand rejected under 35 U.S.C. 112, first paragraph, for reasons of record set forth in the action mailed on 21 August 2002 in Paper NO:7, pages 6-9.

Specifically, the fact that claimed nucleic acid maps on human chromosome 2, 2q11-12, does not provide specific or substantial utility for the claimed nucleic acid, because there is no information regarding the association of the claimed nucleic acid and any disease. Thus, one of ordinary skill in the art would not know how to use the claimed nucleic acid. Furthermore, since the polymorphisms identified for the nucleic acid of SEQ ID NO:3, are not associated with a specific condition, one of ordinary skill in the art would be able to predict which conditions that might be associated with these polymorphisms and therefore, would know how to use said polymorphism, to identify subjects that might be susceptible for a certain disorder.

New Rejections:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 32-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5a. Claims 32, 34, 35 and 36, are indefinite because the claims recites "...encompassing an allele at amino acid 44, ...encompassing an allele at amino acid 51, ...", however, it is unclear whether the DNA of SEQ ID NO:3 encompasses an allelic variant that encodes a threonine or isoleucine at amino acid 44 of the encoded polypeptide (i.e. SEQ ID NO:4), an allelic variant that encodes aspartic acid or alanine at amino acid 51of the encoded polypeptide (i.e. SEQ ID NO:4), or whether SEQ ID NO:3 itself comprises either a threonine or isoleucine at amino acid 44, and aspartic acid or alanine at amino acid 51. Appropriate correction is required.

Claims 33, 37-38 are vague and indefinite so far as they depend on claims 32 and 36 for the limitations set forth directly above.

Conclusion

6. No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday-Thursday, 6:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4227 for regular communications and (703) 308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Fozia Hamud
Patent Examiner
Art Unit 1647
June 2, 2003

GARY KUNZ
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